

## REMARKS

This Amendment is response to the Office Action dated August 13, 2008. Prior to entry of this Amendment, claims 1-58 and 60-144 were pending. This Amendment cancels claims 1-2, 5,8,10-33, 45,48,68,86,89,91,94,118,120, and 123-126. Claims 3-4, 6-7,9, 34-44, 46-47, 49-67, 69-85, 87-88, 90, 92-93, 95-117, 119, 121-122, and 127-160 are now pending. Of these, new claims 145-168 have been added.

### **Support for New Claims and Claim Amendments**

New claims 145 and 154 (capsule formed of materials) find support, for example, at paragraphs 83, 103, 148 and 189.

Support for new claims 146 – 153 and 161-164 (time-release coatings) find support, for example, at paragraphs 54, 99-102, 117-119, 147, 307, 312, 314, 322, 327, 334, 342, 353, 363, and 371. Support for microencapsulation of the solid active agent is found, for example, at paragraphs 294-295.

Support for new claims 155-156 (first receiving chamber enveloping the second receiving chamber) is found, for example, in claim 136.

Support for new claims 158 and 160 (“caffeine”) is found, for example, at paragraphs 377 and 380.

Support for new claims 157, 159, 165-166 (“oil”) and for the addition of the term “oil” in claims 47 and 93 is found, for example, in paragraphs 333, 361 (Vitamin E), 376, 377, 381 – 384, 1555, 1583, 1584, 1592, 1599, 1600, 1608, 1614-1617, 1624-1627, 1642-1643, 1651.

Support for new claims 167-168 is found, for example, at paragraphs 68, 80, 118.

With respect to the changes made in claims 34, 36, 60, 82, 136, 141 and 142, support for the active ingredient in the first receiving chamber being a liquid and the active ingredient in the second receiving chamber being in liquid form is found, for example in paragraphs 48, 49, 62, 63, 997, 98, 311, 355, 373, certain embodiments disclosed in paragraphs 1550-1656, and such situations specifically where and the first receiving chamber envelopes the second receiving chamber is found in paragraphs 355, 373, and certain examples disclosed in paragraphs 1550-1656. Further, support for the phrase “formulated in a manner allowing for a time-delayed dissolution and release of said solid ingredient” is found, for example, at paragraph 314.

The support for the additions made to the claims is exemplary, and additional support is found throughout the specification.

#### **Prior Rejection under 35 USC §102(b)**

In the Office Action, the Examiner agreed that the rejection of claims 1, 5-7, 36, 41-43, 45-47, 49, 122 and 127 as anticipated under 35 U.S.C. 102(b) as being given anticipated by Nowak et al. (WO 01/03676) should be removed given applicant’s argument filed in the response of 5/15/08.

**Prior Rejection Under 35 USC §103(a)**

In the Office Action, the Examiner took the position that applicant's arguments filed on 5/15/08, with respect to the rejection of claims 2, 8-9, 38, 44, 48, 50-53, 106-118, 121, 128 and 137-140 under 35 U.S.C. 103(a) as being unpatentable over Nowak et al. (WO 01/03676) in view of Zimmer (US 5,310,555) were not persuasive.

**Examiner's Response to Declaration of Carey Bottom**

The Examiner took the position that the Declaration of Carey Bottom on 5/15/08 was not found persuasive because "the capsule with at least two separate chambers, as suggested by Nowak, is combined with the capsule with separate chambers in the form of a capsule-in-capsule, as suggested by Zimmer." The Examiner stated that "one of ordinary skill in the art would combine this teaching of Zimmer with the capsule with at least two separate chambers, as suggested by Nowak, and produce the instant invention." The Examiner therefore maintained the rejection of 01/17/08.

**Response to Examiner's Rejection**

Applicant respectfully traverses the Examiner's rejection set forth in paragraphs 7 and 8 of the Office Action dated August 13, 2008. In particular, applicant respectfully asserts that the Examiner has not given sufficient weight to the Declaration of Carey Bottom and failed to appreciate that the combination relied upon would not have resulted in the invention as claimed (previously), without the impermissible use of hindsight based on the accomplishments set forth in the present application.

In particular, Dr. Bottom discusses the fact that Nowak (PCT '676) describes the use of pre-dried film to produce capsules having a septum. (See Bottom Declaration at paragraph 16). Dr. Bottom further explains that the capsules made from the pre-dried film, as described in Nowak were not hard shell capsules. The Examiner apparently accepts this point, and relies on Zimmer to suggest the use of a hard shell double capsule to deliver mutually reactive or

otherwise incompatible substances. However, the Examiner failed to consider, among other things, the further position of Dr. Bottom that (1) the hard shell capsule format was unsuited and inadequate for producing a capsule with a septum, in accordance with Nowak (See paragraph 20 of the Bottom Declaration); that (2) the difficulties in obtaining sufficiently sealed capsule compartments dissuaded BioProgress from attempting actually to manufacture a prototype capsule with a liquid component; that (3) the pre-dried film was unique to and necessary for a capsule with a septum, pursuant to Nowak.

Given the above statements in the Bottom Declaration, the Examiner does not provide the requisite rationale to support a substitution of the material used in the Nowak reference for the hard gelatin used by Zimmer. In fact, the Examiner ignores Dr. Bottom's statement that the Nowak technology was considered to be an advance over, e.g., preexisting hard shell capsule technology. It follows that Dr. Bottom points to a lack of motivation to combine these arts.

The Examiner does not provide any support for the proposition that Zimmer describes a composition which has an ingredient in a first physical state in one receiving chamber, and a different second ingredient in a different physical state in another receiving chamber. In fact, the Examiner appears to incorrectly consider the discussion of Morishita (U.S. 4, 695,466) in Zimmer. In fact, Morishita is mentioned as having two obstacles. First, Zimmer states that the use of oil carriers in Morishita presents insurmountable obstacles to the delivery of bacteria and vitamin supplement components. Second, Zimmer states that it is unlikely that Morishita's soft outer capsules would be able to withstand shipping, storage and administration conditions. Zimmer claimed to solve those problems by using a capsule-in-a-capsule structure. Zimmer never stated that it includes liquid components or oil components. In fact, discussions in the Examples of Zimmer refer to gram weights of ingredients, which appear to be solids, in both of its capsules (in the capsule-in-a-capsule technology).

In view of the above, it is respectfully submitted that without having the benefit of the teachings of the present invention, one of ordinary skill in the art would not have been motivated to use a hard gelatin capsule-in-a-capsule technology for liquids, and that person also would not have considered Nowak to provide a workable composition for liquids, as well. The Examiner

has provided no apparent reason why a person having ordinary skill in the art would modify Nowak in the specified manner to arrive at the (previously) claimed invention, particularly in view of the Bottom Declaration.

The Board of Patent Appeals and Interferences has issued a precedential opinion confirming that:

... obviousness cannot be proven merely by showing that the elements of a claimed device were known in a prior art; it must be shown that those of ordinary skill in the art would have had some "apparent reason to combine the known elements in the fashion claimed ... [Similarly,] obviousness cannot be proven merely by showing that a known composition could have been modified by routine experimentation or solely on the expectation of success; it must be shown that those of ordinary skill in the art would have had some apparent reason to modify the known composition in a way that result in the claimed composition.

*Ex parte Thomas J. Whalen II, Chinh N. Tran, Noah M. Roth, and Richard J. Greff, Appeal No. 2007-4423, Decision of Appeal dated July 23, 2008.*

In any event, the Examiner's rejection is rendered moot by the presently amended claims. The claims have been amended for the sole purpose of moving this application forward to allowance, and applicant reserves the right to pursue the claims as previously presented without prejudice given the current claim changes.

### **New Rejections of Claims Under 35 USC §103**

In the Office Action, the Examiner rejected claims 1-2, 5-9, 36, 38, 41-53, 106-118, 121-122, 127-128 and 137-144 under 35 U.S.C. 103(a) as being unpatentable over Nowak et al. (WO 01/03676) in view of Zimmer (US 5,310,555). The Examiner took the position that it would have been obvious to one of ordinary skill in the art at the time the invention was made to make a capsule with at least two separate chambers and where different chambers of the capsule contain different materials, in different physical forms, as suggested by Nowak, combine it with the capsule with separate chambers in the form of a capsule-in-capsule (where the top member of the capsule is locked with the bottom member of the capsule), as suggested by Zimmer, and produce the instant invention.

Applicant respectfully traverses the Examiner's rejection, for reasons set forth above as well as for other reasons.

In any event, the independent claims in the application have been amended to call for, *inter alia*, a multi-compartment capsule having a first receiving chamber comprising at least one ingredient in a liquid state in immediate release form, and a second receiving chamber comprising at least one ingredient in a solid state, formulated in a manner allowing for a time-delayed dissolution and release of said solid ingredient. The ingredient of the first receiving chamber is different from the ingredient of the second receiving chamber, and the multi-compartment capsule is a hard shell capsule.

These limitations are found in claims 36, 141 and 142 (albeit in the form of means plus function language) currently pending in this application. It is respectfully submitted that the combination of Nowak and Zimmer do not suggest a compartment having an ingredient in liquid state in immediate release form, and a separate compartment containing an ingredient in solid form which is provided which allows for a time-delayed dissolution and release of the same.

Further, it is respectfully submitted that the combination of Nowak and Zimmer do not suggest a multi-compartment capsule where the second receiving chamber is located within the first receiving chamber, as set forth in claims 36, 155 and 156.

Further, it is respectfully submitted that the combination of Nowak and Zimmer do not suggest a multi-compartment capsule where the liquid ingredient in the first receiving chamber is an oil, as set forth, e.g., in claims 7, 47, 157, 159, 165 and 166.

Further, it is respectfully submitted that the combination of Nowak and Zimmer do not suggest a multi-compartment capsule where the release of the solid ingredient is delayed by a time-release coating, or where the solid ingredient is encapsulated with a time-release coating, as set forth, e.g., in claims 146-153 and 167-168.

In view of the above, and for other reasons, the Examiner is respectfully requested to remove the rejection based on the combination of Nowak and Zimmer.

**Rejection over Nowak, Zimmer and Rashid**

In the Office Action, the Examiner took the position that claims 3-4, 37 and 39 are rejected under 35 U.S.C. 103(a) as being unpatentable over Nowak et al. (WO 01/03676) in view of Zimmer (US 5,310,555) and further in view of Rashid et al. (US 5,750,143). The Examiner took the position that it would have been obvious to one of ordinary skill in the art at the time the invention was made to make a capsule with at least two separate chambers and where different chambers of the capsule contain different materials, in different physical forms, as suggested by Nowak, combine it with the capsule with separate chambers in the forms of a capsule-in-capsule (where the top member of the capsule is locked with the bottom member of the capsule), as suggested by Zimmer, further combine it with reducing the dead volume space by using a cap with a different configuration, as suggested by Rashid, and produce the instant invention.

The Examiner's rejection based on the combination of Nowak, Zimmer and Rashid is respectfully traversed. It is respectfully submitted that the combination of these three references do not overcome the deficiencies of the combination of Nowak and Rashid as discussed above.

Further, it is respectfully submitted that the combination of Nowak, Zimmer and Rashid do not suggest a multi-compartment capsule where the second receiving chamber is located within the first receiving chamber, as set forth in claims 36, 155 and 156.

Further, it is respectfully submitted that the combination of Nowak, Zimmer and Rashid do not suggest a multi-compartment capsule where the liquid ingredient in the first receiving chamber is an oil, as set forth, e.g., in claims 7, 47, 157, 159, 165 and 166.

In view of the above, and for other reasons, the Examiner is respectfully requested to remove the rejection based on the combination of Nowak, Zimmer and Rashid.

**Rejection over Nowak, Zimmer and Story**

In the Office Action, the Examiner took the position that claim 40 is rejected under 35 U.S.C. 103(a) as being unpatentable over Nowak et al. (WO 01/03676) in view of Zimmer (US 5,310,555) and further in view of Story (US 5,738,871). In the Office Action, the Examiner took the position that it would have been obvious to one of ordinary skill in the art at the time the invention was made to make a capsule with at least two separate chambers and where different chambers of the capsule contain different materials, in different physical forms, as suggest by Nowak, combine it with the capsule with separate chambers in the form of a capsule-in-capsule (where the top member of the capsule is locked with the bottom member of the capsule), as suggested by Zimmer, further combine it with reducing the dead volume space by using filling material such as surfactants, as suggested by Story, and produce the instant invention.

The Examiner's rejection based on the combination of Nowak, Zimmer and Story is respectfully traversed. It is respectfully submitted that the combination of these three references do not overcome the deficiencies of the combination of Nowak and Zimmer as discussed above. Story describes embodiments where a surfactant can be present for filling the capsules.

Further, it is respectfully submitted that the combination of Nowak, Zimmer and Story do not suggest a multi-compartment capsule where the second receiving chamber is located within the first receiving chamber, as set forth in claims 36, 155 and 156.

Further, although Story describes the inclusion of oils in its hard gelatin capsules, it is respectfully submitted that the combination of Nowak, Zimmer and Story do not suggest a *multi-compartment* capsule where the liquid ingredient in the first receiving chamber is an oil, as set forth, e.g., in claims 7, 47, 157, 159, 165 and 166.

Further, it is respectfully submitted that the combination of Nowak, Zimmer and Story do not suggest a multi-compartment capsule where the release of the solid ingredient is delayed by a

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- time-release coating, or where the solid ingredient is encapsulated with a time-release coating, as set forth, e.g., in claims 146-153 and 167-168.

In view of the above, and for other reasons, the Examiner is respectfully requested to remove the rejection based on the combination of Nowak, Zimmer and Story.

**Conclusion**

An early and favorable action on the merits is earnestly solicited. According to currently recommended Patent Office policy, the Examiner is specifically authorized to contact the undersigned in the event that a telephonic interview will advance the prosecution of this application.

Respectfully submitted,  
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